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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,860

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Robert Douglas

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EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,860	Applicant(s) DOUGLAS ET AL.	
	Examiner KRISTEN C. MATTER	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19,22,23,30-34,36-38,40,43-48,50,53,54,61-65,67-69,71 and 74-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,22,23,30-34,36-38,40,43-48,50,53,54,61-65,67-69,71 and 74-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the amendment filed 2/14/2011. Claims 19, 34, 50, 65 and 67 have been amended, claims 35 and 66 have been cancelled and no claims have been added. Thus, claims 19, 22, 23, 30-34, 36-38, 40, 43-48, 50, 53, 54, 61-65, 67-69, 71, and 74-79 are currently pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 22, 23, 30-34, 36-38, 40, 43-48, 50, 53, 54, 61-65, 67-69, 71, and 74-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froehlich et al. (US 5,551,419, herein referred to as “Froehlich”) in view of Berthon-Jones (US 5,704,345) and Hill (US 2002/0088465).

Regarding claims 19, 34, 36-38, 43, 50, 54, 65, 67-69, and 74, Froehlich discloses CPAP apparatus having a blower (12), a patient interface (11), an air delivery conduit (14), a pressure sensor (16), a flow sensor (15), an air synchrony module to determine transitions between inhalation and exhalation (see column 2, lines 60-65 and column 6, lines 15-20 for example), and a control mechanism (17) programmed to provide positive pressure in accordance with a predetermined pressure-time template (see Figure 4). Froehlich further discloses that the apparatus controls blower operation by automatically determining the presence of sleep

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disordered breathing and automatically determining a treatment pressure in accordance with the presence of sleep disordered breathing (column 5, lines 35-55), setting at least one characterizing parameter of the pressure-time template to the treatment pressure (column 6, lines 15-27 and column 13, lines 20-30), and controlling the blower to delivery a supply air in accordance with the template and in synchrony with the patient's breathing cycles (via lines 19 and 20).

Froehlich discloses determining sleep disordered breathing, such as apnea, from "known techniques" but is silent as to how exactly the presence of those events are determined.

However, indices are a well known and commonly used means in the art for determining the presence of a sleep disordered breathing event. In addition, Berthon-Jones discloses a similar CPAP apparatus that determines the presence of apneas by calculating several indices, including both an index for indicating apnea and an index indicative of flow flattening (see abstract). The index for calculating apnea is determined from a ratio of the middle points (column 10, lines 35-40), while the flow flattening index is calculated from the root mean square deviation (column 11, lines 3-7). Thus, the first and second indices are considered as being determined from "different characteristics" of the signals. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used several indices for determining the presence of two sleep disordered breathing events while using the system of Froehlich because it would have allowed a user to use a well known means for determining the presence and/or severity of sleep disordered breathing and to provide therapy as needed. Such a modification would involve the mere substitution of a well known method of determining apnea episodes in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

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Froehlich as modified by Berthon-Jones further lacks setting one pressure parameter to a first treatment pressure in accordance with the first index during expiration and another pressure parameter to a second treatment parameter based on the second index during inspiration, although Froehlich does disclose that the IPAP and EPAP pressures can be independently set (column 6, lines 30-50; both have different input signals and are controlled/set by the processor). In addition, Hill discloses a similar CPAP apparatus that uses several indices to independently vary both the IPAP and EPAP to counter a sleep disordered breathing event (see paragraphs 11, 12, 49, and 53 for example). Hill further discloses in paragraph 53 that while it is always necessary to adjust the IPAP pressure, sometimes it is necessary to also adjust the EPAP when IPAP adjustments are not enough to treat the patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified Froehlich to adjust both the EPAP and IPAP as taught by Hill depending on the severity of the sleep disordered breathing event and/or to treat the patient more comfortably by adjusting both the minimum and maximum pressures only as necessary. Either the indices of Hill, which are determined from different characteristics (i.e., peak flow) than those of Berthon-Jones, could be used solely for EPAP adjustment while Berthon-Jones are used for IPAP adjustment or Berthon-Jones's indices could be used individually for IPAP and EPAP since Berthon-Jones discloses that the indices may be used individually (column 11, lines 19-23) and that pressure is a well known means for determining the presence of sleep apnea (see column 2, lines 1-10). Furthermore, there is nothing structurally in Froehlich that would prevent the controller from adjusting both the EPAP and IPAP based on the separate events/indices and it appears as though Froehlich would perform equally well with both the EPAP and IPAP being adjusted.

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Regarding claims 22, 44, 53, and 75, Froehlich discloses the template can be a square wave (see column 2, line 64).

Regarding claims 30, 40, 61, and 71, Froehlich does not specifically disclose a maximum swing/pressure difference. However, absent a critical teaching and/or showing of unexpected results from having a maximum swing, examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a maximum swing in order to prevent the swing from getting too large if a high number of sleep disorder breathing events was detected, to increase comfort to the patient by keeping the maximum and minimum pressure levels closer to one another, and to allow the device to effectively get to the desired min/max pressure levels (i.e., if the swing is too large the system might not be able to reach the desired pressures in the given amount of time of the breathing cycle). In addition, since the pressures are generally between 3-20 cmH₂O in CPAP systems, it would have been obvious to ensure that the pressures stayed within this range, and thus are subject to a maximum swing. Furthermore, there is nothing structurally that would prevent the use of a maximum swing and it appears as though the device would work equally well with a maximum swing when increasing/decreasing the pressure.

Regarding claims 31, 32, 47, 48, 62, 63, 78, and 79, Froehlich, Berthon-Jones, and Hill all disclose decreasing pressures in the absence of sleep disordered breathing events (see column 1, lines 55-60 of Froehlich and paragraphs 13, 51, 69, 72, and 75 of Hill for example). It thus would have been obvious to adjust the first and second treatment pressures in accordance with the absence of events determined by their respective indices.

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Regarding claims 33, 46, 64, and 77, Froehlich does not specifically mention a look-up table. However, the controller is programmable and look-up tables and arrays are well known and commonly use processing techniques for creating signals. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have had the breathing signal be derived from a look-up table or array because it would have provided a well known means of creating a safe breathing profile for a user. Such a modification would appear to involve the mere substitution of a well known method in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Regarding claims 45 and 76, Froehlich lacks the template being a shark-fin wave. However, shark-fin waves are well known and commonly used in CPAP systems as evidenced by Hill (see Figure 4 for example). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a shark-fin wave in the template of the modified Froehlich device in order to more comfortably delivery gas to a patient by making pressure changes less abrupt for example. Furthermore, there is nothing structurally preventing the use of a shark-fin wave (or any other well known waveform for that matter) in Froehlich's system and it appears as though Froehlich would perform equally well with a shark-fin wave. Such a modification would involve the mere substitution of a well known method/waveform in a well known device to yield predictable results that do not patentably distinguish an invention over the prior art.

Response to Arguments

Applicant's arguments filed 2/14/2011 have been fully considered but they are not persuasive.

Regarding applicant's argument that the prior claimed indices are different from determining the presence of sleep disordered breathing events, examiner notes that an index is simply a means of determining the presence of a sleep disordered breathing event as discussed in the above rejection. By determining indices in the modified Froehlich device, the system is determining the presence of sleep disordered breathing events because it is using numerical values lying within certain ranges to represent the presence of a particular sleep disordered breathing event. Thus, the amendment to the claims seems to make the claims more broad and does not distinguish them over the prior art.

In response to applicant's arguments that the events in the prior art are not determined independently of each other, examiner notes that Froehlich discloses separate signals for setting IPAP and EPAP as well as determination of the presence of a sleep disordered breathing event using known techniques, Berthon-Jones determines two disordered breathing events (apnea and flow flattening) from different characteristics of a flow signal and also discloses that pressure signals are a well known means for determining apnea, and Hill discloses using several indices to independently control IPAP and EPAP adjustment as needed based on severity or when adjustment of IPAP alone isn't enough to counter the disordered breathing as discussed above. Therefore, it would have been well within the knowledge of one of ordinary skill in the art at the time the invention was made to have used the teachings of Froehlich, Berthon-Jones, and Hill to arrive at the instant invention. Mainly, one could have used pressure signals for determining

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apnea and flow signals for determining flow flattening in the same manner described by Berthon-Jones, or used Berthon-Jones indices combined with Hills indices to determine several types and/or the severity of disordered breathing (as taught by Berthon-Jones) and to adjust IPAP and EPAP pressure independently as needed based on the presence of more severe sleep disordered breathing (as taught by Hill) in the device of Froehlich since they are well known techniques and Froehlich discloses determining disordered breathing and adjusting both IPAP and EPAP. Since the presence of both flow flattening and apnea would seem to indicate more severe disordered breathing, it is obvious to use the presence of one to adjust just the IPAP for example and the presence of the other/both to also adjust the EPAP (independently of the IPAP adjustment as taught by Hill) since it is likely that more pressure support will be needed for an apneas in which a closed airway is also occurring.

In response to applicant's arguments that Berthon-Jones and Hill use a single signal, examiner notes that as discussed above, Berthon-Jones discloses that pressure signals are a well known means for determining apneas as well, and thus that teaching could be used to determine the apnea with the flow flattening being determined in the same manner as Berthon-Jones discloses. Likewise, the indices of Berthon-Jones and Hill could be combined in one device and used together to determine the disordered breathing events and thus also represent different signals. Examiner also contends that there appears to be no criticality to either Berthon-Jones or the instant invention whether the events are determined from a single signal or two separate ones since the same information is being determined in each and the result would be the same for a particular breath regardless of how many signals were used to determine the indices/events. Furthermore, flow and pressure are directly correlated in breathing systems and whether "flow"

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or "pressure" is measured is an obvious design consideration to one of ordinary skill in the art depending on the capabilities of the processor and what type of sensor in particular is desired.

Applicant further argues that Hill is solely used for treatment of CSR and not apneas. However, Hill discloses treatment of sleep apnea in the abstract, throughout the background section, and in paragraphs 11 and 47 for example. Thus, it appears that Froehlich's device would work equally well with the methods of Hill, either by use of Hill's index calculations themselves for adjusting EPAP or at a minimum Hill's teaching that adjustment of EPAP in addition to IPAP is sometimes necessary. Examiner concedes that Hill does not "anticipate" the instant invention, merely that the teachings of Hill in combination with Froehlich and Berthon-Jones would have been obvious to one of ordinary skill in the art to arrive at the instant invention (i.e., again, Berthon-Jones teaches identifying two different types of characteristics/events and Hill discloses adjustments of different ones of IPAP and EPAP which would have been obvious in the system of Froehlich).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771